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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,624	07/15/2003	Paolo Pirazzoli	02508.0087	4701

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,624

Applicant(s)

PIRAZZOLI ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. PCT/IB00/01069.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5 and 7-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,471,872 to Kitaevich et al.

In the specification and figures, Kitaevich discloses the invention as claimed by applicant. In particular, Kitaevich discloses a dialysis system with a hemofilter 24 with a semipermeable membrane that divides the hemofilter into a blood compartment and a diasylate compartment. The filter retains cellular components of the blood while certain components are extracted to the diasylate side through the hemofilter (see column 7, lines 1-15). The invention further comprises a blood circuit connected to the hemofilter (generally at 14, 30) with pump 16, inlet and outlet connections to the filter, a diasylate circuit with pumps 60, 66, connected to the filter, various detectors, a controller or calculator 12, and a display 13 that generates a display of the measured and calculated parameters (see column 6, lines 15-67, FIG 1).

Kitaevich further discloses that blood from the patient is circulated via input line 14 through hemofilter 24 where solutes flow through the membrane (see column 7, lines 1-15). Kitaevich discloses that the system monitors various parameters, including fluid pressure in the circuit and hematocrit, evaluates the parameter data (which may include

calculating the rate of filtration), and generates control signals that adjust the pumping rate of the diasylate or the blood (see column 3, lines 40-67, column 4, lines 1-5, column 8, lines 7-20).

With regard to claims 2 and 5, Kitaevich further discloses that when the ultrafiltration rate deviates from a preselected desired rate, the controller generates control signals that adjust the fluid flow rates.

With regard to claims 3 and 11, Kitaevich discloses that the system may measure flow rates through the tubing (which includes a blood flow rate) and an ultrafiltration rate (see generally, column 7). The controller 12 has broad authority to control modification of fluid pumping rates based on the measured patient parameters (see column 9, lines 52-57).

With regard to claims 7 and 8, Kitaevich discloses that pressure transducers 20, 26, 34, and 70 detects the pressure at the inlets and the outlets of the compartments (see FIG 2, column 8, lines 32-40).

Kitaevich discloses that the display 13 offers a visual representation of various measured and computed parameters, such as flow rates, ultrafiltration, and alarm conditions. Therefore, Kitaevich discloses a device that detects flow rates, a controller that calculates and compares measured values to reference values, controls the pumps, and generates alarm signals.

With regard to claims 9-15 drawn to the operation of the dialysis device, such limitations are held to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to

be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 4, 6-9, and 11-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-10 of U.S. Patent No. 6,730,233 to Pedrazzi. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims present a dialysis machine with a "means for" carrying out the method claimed in the instant application. Therefore, the machine in the patent not only is capable of performing the claimed method, but actually does so. Therefore, the instant application is unpatentable over the claims of the previously patented invention.

With regard to claim 15, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place additional pumps in the device claimed by Pedrazzi, since it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. See MPEP § 2144.04.

5. Claims 5, 16, and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,730,233 to Pedrazzi in view of US 6,471,872 to Kitaevich et al, as applied above. Pedrazzi claims a machine with "means for" performing the method as claimed in the instant application, with the exception of checking whether the filtration factor is below a predetermined value. Kitaevich discloses that in his method, the calculator/controller constantly compares measured values to predetermined values to ensure that the

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device is operating within predetermined safe parameters. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the checking step to the device with "means for" performing the claimed method as claimed by Pedrazzi in order to ensure safe operating parameters, as taught by Kitaevich.

6. Claims 9, 11, and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5 of U.S. Patent No. 6,966,979 to Pedrazzi. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented invention includes all the components of the instantly claimed device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the components of the patented device (such as the dilution pipes) in order to create the instantly claimed device, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. See MPEP § 2144.04.

Response to Arguments

7. Applicant's amendment filed 16 December 2005 has been entered and considered. The amendment has overcome the rejections under 35 USC §§ 101 and 112, and the rejections have been withdrawn.

8. Applicant's arguments filed 16 December 2005 with regard to claim 9 have been fully considered but they are not persuasive.

Applicant argues that the Kitaevich device fails to disclose a calculator “for calculating...” specific parameters. Such limitations are held to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 5,702,597 Chevallet et al
 - i. Dialysis device with transmembrane pressure measurements

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

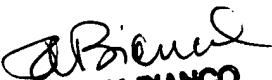
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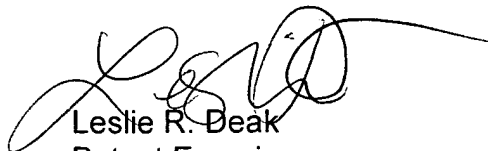
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PATRICIA BIANCO
PRIMARY EXAMINER
2/28/06


Leslie R. Deak
Patent Examiner
Art Unit 3761
28 February 2006